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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,577	10/23/2003	Lilip Lau	PARCR 65971	1087

24201 7590 12/14/2005

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
GILBERT, SAMUEL G	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,577	LAU ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54,55,57,60-63 and 66-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,55,57,60-63 and 66-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/2005 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54, 55, 57, 60-63 and 66-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (6,360,749) in view of Lau et al (6,517,570).

Jayaraman teaches a medical device, figures 6B, 7B, 7C, 8A, 8B-12 and 14 for treating the heart including elastic bands adapted to extend circumferentially around an outer surface of the heart but does not teach the material including a plurality of hinge elements. Jayaraman does set forth that stent graft materials may be used column 12 lines 19-29. Lau et al. sets forth a plurality of embodiments of stent graft material formed by a plurality of hinge elements, the embodiments of figures 3, 4, 5, 6, 8, 10, 11,

12, teach non-overlapping hinge elements. Lau et al sets forth that the hinged elements provide the advantage of being foldable to be delivered intraluminally, kink-resistant and self-expanding. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the stent graft material taught by Lau et al. to be used for the stent graft material set forth to provide the benefits as described above to the cardiac treatment device of Jayaraman. Lau et al. further teaches the use of non-overlapping hinge elements with torsion bars provide the advantage of allowing the device to be formed from a flat sheet and having torsional balance by spreading the load when the material is folded into a small diameter, column 12 lines 1-8.

Claim 55 - the hinge elements of Lau et al are "self-sizing" and the cardiac device of Jayaraman is adapted to extend circumferentially around the heart.

Claim 57 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are inherently "self-tensioning".

Claims 60 and 61 – the compliance is an inherent feature of the hinge elements set forth in figures 1A-1E of Lau et al.

Claim 62 – Jayaraman teaches strips that extend circumferentially around the heart.

Claim 63 – the material of Lau et al. provide a compressible to a low profile. Further Jayaraman teaches minimally invasive delivery, applicant's attention is invited to column 11 lines 32-44. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 66 – Lau et al teaches the use of Nitinol, column 12 lines 31 and 32.

Claim 67 – the Nitinol hinge elements of Lau et al inherently have a deformed shape and a recovered shape.

Claim 68 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 69 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 70 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Response to Amendment

The declaration of Lilip Lau filed on 11/21/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Jayaraman reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Jayaraman reference. While conception is the mental

part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The examiner agrees with paragraphs 1-5.

Regarding paragraph 6 - the examiner disagrees that there was conception before 10/8/1999. Conception has been defined as "the complete performance of the mental part of the inventive act" and it is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice.." *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1930). "[C]onception is established when the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill." *Hiatt v. Ziegler*, 179 USPQ 757, 763 (Bd. Pat. Inter. 1973). Conception has also been defined as a disclosure of an invention, which enables one skilled in the art to reduce the invention to a practical form without "exercise of the inventive faculty." *Gunter v. Stream*, 573 F.2d 77, 197 USPQ 482 (CCPA 1978). See also *Coleman v. Dines*, 754 F.2d 353, 224 USPQ 857 (Fed. Cir. 1985) (It is settled that in establishing conception a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged conception. Conception must be proved by corroborating evidence.); *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F. 2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986) (Conception is the "formation in the mind

of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."); *Hitzeman v. Rutter*, 243 F.3d 1345, 58 USPQ2d 1161 (Fed. Cir. 2001) (Inventor's "hope" that a genetically altered yeast would produce antigen particles having the particle size and sedimentation rates recited in the claims did not establish conception, since the inventor did not show that he had a "definite and permanent understanding" as to whether or how, or a reasonable expectation that, the yeast would produce the recited antigen particles.).

After reviewing the notebook entries supplied as evidence it is the examiner's position that the work being done by the applicant's prior to 10/8/1999 was directed to devices hoped to be capable of treating congestive heart failure and more specifically to devices used **inside the heart** not outside the heart. The applicant's evidence includes pages of work directed to anchors for just such a purpose, while the claimed invention does not include anchors, an essential element for a device used inside the heart. The general concept was to apply a compressive force to the inside of the heart. The evidence provided does not raise to the level of conception for the claimed invention.

Further, no disclosure is set forth regarding a plurality of hinge elements. The examiner did not find the term "hinge element" in the evidence provided. The closest reference to what might be considered a hinge element is set forth in the notebook of Lau pages 50, "reinforcement would be spring-like" and on page 52, "a spring mechanism such as a coil" It is the examiner's position that this does not meet the definition of conception..."the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied

in practice.." *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1930). Because the mere mention of "spring –like" and "spring mechanism" does not set forth the ..."the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice.." in this case a plurality of non-overlapping hinge elements.

Even further, the examiner did not find any evidence of ***"non-overlapping"*** hinge elements. To the contrary the sketch on page 52 of the Lau notebook shows overlapping coils. A coil itself by definition overlaps itself. Further, the examiner would like to point out the extensive experimentation and inventive work done after 10/8/1999 before the claimed invention was reduced to practice.

The first evidence of use of a cardiac jacket on the outside of the heart is set forth 10/25/2005, page 79 "epicardial surface".

Regarding paragraph 7 - the examiner agrees that that a problem to be solved is set forth "treatment of congestive heart failure" and that a number of medical devices and methods of use are set forth.

Regarding paragraph 8 – the examiner does not agree that claim 54 is supported prior to 10/8/1999. The claimed invention [claim 54] includes at least "a medical device comprising a plurality of non-overlapping hinge elements adapted to extend circumferentially around an outer surface of the heart to impart compressive force on the heart during diastole and systole...". It is the examiner's position that the work prior to 10/8/1999 was directed to a harness to be implanted inside the heart no evidence

supports any work being done on a harness for outside the heart. At least one major difference exists between a cardiac harness for inside the heart and a harness for outside the heart, that difference being that a device used inside the heart must be anchored to the heart wall to provide a compressive force to the heart wall. The applicant's evidence includes pages of work directed to anchors for just such a purpose, while the claimed invention does not include anchors, an essential element for a device used inside the heart. The work is delivered into the ventricle using a "femoral approach" page 48, with the anchors placed in the endocardial surface, throughout the pages, and the anchors would be "driven into and hold onto the myocardium without penetrating out to the epicardial surface" page 52.

The examiner agrees that at page 50 "spring-like" is set forth, however it is the examiner's position that "spring-like" does not set forth "non-overlapping hinge elements adapted to extend around an outer surface of the heart".

The examiner agrees that page 52 sets forth several embodiments including a "zig-zags" but it appears that the nodes of the straight line and "zig-zags" as shown are connected by non-distensible string. A zig zag coil spring embodiment is also shown, which the applicant argues provides support for "non-overlapping hinge element that are adapted to extend circumferentially around an outer surface of the heart...". It is the examiners position that the coils as shown in the sketch are overlapping not "non-overlapping. Further, even if the coils in the zig zag pattern are non-overlapping, it is the examiner's position that the coils themselves are overlapping and therefore would not support the "non-overlapping" claim language.

The examiner agrees that on page 57 that "spring members" are set forth however they are again for use inside the ventricle not outside the heart. Further, the broad recitation of "spring-members" does not support "non-overlapping hinge elements adapted to extend circumferentially around an outer surface of the heart.

The examiner agrees that page 58, sets forth delivered "endovascularly through a catheter" which does support a device delivered minimally invasively, however the device would be inside the heart not a device adapted to extend circumferentially around an outer surface of the heart.

Regarding paragraph 9 – for the reasons above and further, the coil may be self sizing but it is inside the heart.

Regarding paragraph 10 – see 7-9 above. The spring coil may be considered self tensioning.

Regarding paragraph 11 – as above and further, the coil-spring does not set forth "hinge elements" and the examiner agrees that the compliance of a coil-spring would function as claimed.

Regarding paragraph 12 – as above and further, the coil-spring does not set forth "hinge elements" and the examiner agrees that the compliance of a coil-spring would function as claimed.

Regarding paragraph 13 – see above for the coil-spring and on page 58, both embodiments are disclosed for use inside the heart. Further, no evidence is set forth to indicate the barbs do anything but anchor the device. The barbs are not "hinge elements" to self tension and self size the device.

Regarding paragraph 14 –on page 58, both embodiments are disclosed for use inside the heart. Further, no evidence is set forth to indicate the barbs do anything but anchor the device. The barbs are not "hinge elements" to self tension and self size the device.

Regarding paragraph 15 – no pages 127 and 131 have been provided.

Regarding paragraph 16 – the examiner does not agree "hinge elements" have been set forth however the device is delivered through a catheter to the inside of the heart.

Regarding paragraph 17 – the examiner does not agree "hinge elements" have been set forth however the device is delivered through a catheter to the inside of the heart.

Regarding paragraph 18 – the examiner does not agree "hinge elements" have been set forth however the device is delivered through a catheter to the inside of the heart.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Jayaraman reference to either a constructive reduction to practice or an actual reduction to practice. The evidence provided by the applicant show a large number of lab journal entries between 10/8/1999 and the date of reduction to practice however the vast majority of them are directed to an apparatus for internal use in the heart and devices not including "spring elements" even if the "spring elements can be argued to teach hinge elements. Most of the entries are directed to anchors, devices for implanting anchors or devices in which a tether line of some sort is

connected between the anchors to treat congestive heart failure. The applicant has failed to show even a modicum of constant work on the claimed invention.

The declaration of Bill Hartigan filed on 11/21/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Jayaraman reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Jayaraman reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The examiner agrees with paragraphs 1 and 2.

Regarding paragraph 3 – no evidence has been provided to show conception of the claimed invention prior to 10/8/1999. Page 1 of the notebook is the only evidence provided detailing work from before 10/8/1999 and it is the examiner's position that page 1 does not show a plurality of non-overlapping hinge elements adapted to extend circumferentially around the outer surface of the heart.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Jayaraman reference to either a constructive reduction to practice or an actual reduction to practice. The evidence provided by the

applicant show a large number of lab journal entries between 10/8/1999 and the date of reduction to practice however the vast majority of them are directed to an apparatus for internal use in the heart and devices not including "spring elements" even if the "spring elements can be argued to teach hinge elements. Most of the entries are directed to anchors, devices for implanting anchors or devices in which a tether line of some sort is connected between the anchors to treat congestive heart failure. The applicant has failed to show even a modicum of constant work on the claimed invention.
Work on devices for the outside the heart are set forth only on page 14, 11/3/1999and pages 53-58, dated 3/16/2000.

The declaration of Darrell H. Ogi filed on 11/21/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Jayaraman reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Jayaraman reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The examiner agrees with paragraphs 1 and 2.

Regarding paragraph 3 – no evidence has been provided to show conception of the claimed invention prior to 10/8/1999. Pages 1-5 of the notebook provide evidence

of anchors and metal strips used inside the heart not "non-overlapping hinge elements adapted to extend circumferentially around the outer surface of the heart."

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Jayaraman reference to either a constructive reduction to practice or an actual reduction to practice. The evidence provided by the applicant show a large number of lab journal entries between 10/8/1999 and the date of reduction to practice however the vast majority of them are directed to an apparatus for internal use in the heart, anchors, devices for implanting anchors or devices in which a tether line of some sort is connected between the anchors to treat congestive heart failure. The applicant has failed to show even a modicum of constant work on the claimed invention.

Notebook pages 97 through 107 appear to set forth work on the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571-272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg